Performance of three portable blood glucose monitoring devices used in a veterinary application

Prepared by Michael I. Lindinger, PhD, Vice-President of Research,

The Nutraceutical Alliance, Campbellville, ON L0P 1B0, Canada

Abstract

The paper reports on the results of testing three portable blood glucose monitors (PBGMs) designed for the veterinary market. The results of the testing were used to assess system accuracy and clinical accuracy. Blood samples from 26 dogs and 20 cats were tested using a clinical reference system and each of the three PBGMs. Some of the blood samples were spiked with concentrated glucose solution to elevate sample glucose concentration. Varying numbers of test strip lots were tested with each PBGM. System accuracy was assessed using Bland-Altman analysis and linear regression analysis. Clinical accuracy was assessed using the Parkes error grid analysis. Analysis showed that all three PBGMs reported data that were not statistically, significantly different from the clinical reference method. However, the iPet PRO device showed significantly less bias and less variability than the other two devices. It is concluded that the iPet PRO PBGM met or exceeded analysis criteria and was excellent in performance.

Introduction

The ability to accurately measure blood glucose concentration is important when knowledge of the glycemic state of diabetic dogs and cats if required. Effective nutritional management of diabetes in cases of both reduced insulin production and insulin resistance helps maintain stable blood glucose concentrations and avoids complications associated with excessively low or high blood glucose (Peterson and Eirmann 2014).

In response to this need a number of companies have developed portable, point-of-care, blood glucose measuring instruments (PBGMs), most often using a solid-state interface such as a glucose test strip. Early devices had challenges associated with accuracy and precision (for review see Inoue et al. 2013) although could provide a 'guideline' of blood glucose concentration. Early technology also had a relatively narrow operating range, not ideal for the large excursions in blood glucose concentrations that may occur in diabetic animals.

The technology of PBGMs has continued to improve to the point where they were deemed useful in clinical practice (Wess and Reusch 2000). The criteria against which portable PBGMs are published in the International Standards Organization (ISO) monograph 15197:2013 In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197; 2013). While these criteria were developed for the human market, the standards are applicable to the animal health care market. Minimum performance criteria are centered on "system accuracy" (the concept includes measurement bias and measurement precision), defined as the ability to produce measurement results that agree with true glucose values when the system is used as intended (ISO 15197:2013).

Instruments designed for human use have been assessed for their use in dogs (Wess and Reusch 2000; Cohen et al. 2009; Johnson et al. 2009; Domori et al. 2014) and cats (Zini et al. 2009; Domori et al. 2014; Kang et al. 2016). Veterinary devices have been developed and tested (Johnson et al. 2009; Zini et al. 2009; Kang et al. 2016). There are appreciable differences in accuracy between devices (Cohen et al. 2009) and PCV can be a confounding variable (Wess and Reusch 2000; ISO 15197:2013). Errors in accuracy are typically large outside of the instrument reference range. Accordingly, Johnson et al. (2009) stressed the importance of using only a single device when monitoring trends in dogs and to stay within instrument-specific reference ranges.

The present study reports on the preliminary results obtained using a new portable PBGM that has very good accuracy over a large operating range as well as good precision when compared against a clinical reference chemistry analyzer.

Methods

Animals. Animals were housed and cared for in accordance with the guidelines of the Animal Welfare Act (US Department of Agriculture, 2013). Male and female dogs (n = 26) and cats (n = 20) of various breeds and ages were used (Table 1). All animals were healthy at the time of testing, and one dog and one cat had insulin resistant diabetes.

Blood sampling and handling. Venous blood was obtained from either the jugular, cephalic, or saphenous vein using a 3 cc plastic syringe fitted with a 22G needle. The whole blood sample was immediately transferred into a lithium heparinized collecting tube and mixed completely. From this, 1.5 µL of blood was withdrawn by 10 µL pipette and applied to the target area of the test strips. A minimum 0.7 µL blood was automatically drawn into test strip, then the meter initiated the analysis. The test result appeared on the display in 5 seconds.

Whole blood was applied directly to the test strips for each PBGMs. The remaining blood sample was centrifuged 10 min at 2500 rpm. Plasma was removed and submitted for analysis by the reference method of a hospital chemistry analyzer (IDEXX Catalyst One Chemical Analyzer), which was located at the same test site. To avoid glucose consumption in the sample, all measurements were performed consecutively, with a maximum delay of 10 minutes between sampling and testing. All devices were operated and calibrated according to the manufacturers' instructions. To reduce the operator error, the procedures were conducted by trained technicians.

In order to create blood samples with elevated glucose concentration, an appropriate volume (≤1% of the blood sample volume) was added to some of the blood samples (Table 2). Samples were thoroughly and gently mixed prior to administration to each test strip.

Instrumentation

Reference Method. The IDEXX Catalyst One Chemical Analyzer (IDEXX Laboratories, Inc., Westbrook, Maine 04092, USA) was used as the reference method. This instrument was maintained and calibrated according to international standards (ISO 9001:2008; ISO 17025:2005; ISO 14001:2004).

Three commercially available PBGMs were evaluated: the iPet PRO (UltiMed, Excelsior, Minnesota 55331, USA); the AlphaTRAK 2 (Zoetis, Parsippany, NJ 07054, USA); and the Accu-Chek Performa (Roche Diabetes Care, Inc., Indianapolis, IN 46256, USA). All instruments were used, calibrated and maintained according to manufacturers' instructions. Key specifications of the three devices are provided in Table 3. Data from these devices were converted, by instrument software, to plasma glucose equivalence.

Table 1. Characteristics of the dogs and cats used in the study, and of the hematocrit (HCT) of the blood sample.

Dogs - Breed	Gender	AGE (Y)	HCT (%)		Cats -Breed	Gender	AGE (Y)	HCT (%)
Shiba Inu	F	17	36		Chinchilla	M	3~8	35
Poodle	F	3~8	28		Chinchilla	M	1.5	46
Chihuahua	M	2	46.5		Chinchilla	M	11	29
Poodle	F	3~8	28		*Chinchilla	M	1.5	38
Golden Retriever	F	13~18	41		Mix	M	1	33
Old English Sheepdog	F	2	44		Mix	M	3	13.9
*Golden Retriever	F	13~18	31		Mix	M	2	43
Mix	M	1	28		Mix	M	3	48
Shiba Inu	M	1.5	40		Mix	F	0.5	39
Mix	M	5	52		Mix	F	13	39
Poodle	M	7	46.3		Mix	M	13	40
Mix	M	5.5	41		Persian	M	10	40
Mix	F	6.5	35.6		Mix	M	2	39
Shiba Inu	M	2.5	27.2		Mix	M	2	39.3
Poodle	F	5.5	52.5		Mix	M	4	52.5
Mix	M	3	39		Mix	F	2	42.1
Sheltie	M	10	43		Mix	M	13	19.8
Mix	M	10	29		Mix	F	2	48.9
Pug	F	7	36		Mix	M	3	46.4
Chihuahua	F	10	50		Mix	F	7	46.1
Mix	M	1.5	48					
Mix	F	2	48					
Mix	F	2	48					
Mix	F	2	48					
*Poodle	F	2.5	46					
MIX	M	0.2	13.4					

* Indicates diabetic animal

Table 2. Reference glucose concentrations and animal used for blood samples that were spiked with concentrated glucose solution in order to elevate sample glucose.

IDEXX glucose (mg/dL)	Dogs - Breed	Gender	AGE (Y)		IDEXX glucose (mg/dL)	Cats - Breed	Gender	AGE (Y)
96	Chihuahua	M	2		275	Chinchilla	M	1.5
360					262			
85	Poodle	F	3~8		160	Mix	F	13
108					366			
130	Mix	M	1		248			
234					432			
76	Mix	M	1.5		89	Mix	M	13
193					208			
345					309			
406					382			
500					495			
67	Mix	F	2		78	Persian	M	10
186					164			
314					244			
388					391			
482					519			
47	Mix	F	2		84	Mix	M	2
170					193			
347					307			
256					352			
444					464			
65	Mix	F	2					
191								
234								
353								
523								
201								
258								
326								
357	Poodle	F	2.5					
456								

Table 3. Key specifications of the three PBGMs used in the present study.

	iPet PRO	**AlphaTRAK 2**	**Accu-Chek Performa**
Test Principle	Amperometric Biosensor with FAD-Glucose Dehydrogenase	Coulometric electrochemical sensor	Electrochemical; Mutant variant of quinoPROtein glucose dehydrogenase (Mut. Q-GDH)
Measuring Range	20 to 600 mg/dL	20 to 750 mg/dL	10 to 600 mg/dL
Test Time	5 seconds	15 seconds	5 seconds
Sample Volume	0.7 µL	0.3 µL	0.6 µL
Blood Sample	Venous and capillary whole blood	Venous and capillary whole blood	Capillary, venous, arterial, and neonate whole blood
HCT Range	20 - 60 %	15 – 65%	10 – 65%

System accuracy (the ability to produce measurement results that agree with true glucose values when the system is used as intended; ISO 15197:2013) was assessed using Bland-Altman analysis, comparing the PGBM against the IDEXX as reference. Results for each sample analysis were obtained, and these data were subsequently pooled for each instrument. The minimum system accuracy performance criteria (ISO 15197:2013) are: 95 % of the measured glucose values shall fall within ±15 mg/dl of the average measured values of the reference measurement procedure at glucose concentrations <100 mg/dl or within ± 15 % at glucose concentrations ≥100 mg/dl.

Clinical accuracy: 99 % of individual glucose measured values shall fall within zones A and B of the Parkes error grid (Pfützner et al. 2013). The Parkes error grid was developed independent from ISO 15197:2003 criteria (i.e., ±20%7) and specifies a more strict definition for zone B (altered clinical action with little or no effect on clinical outcome). The error grid zones A through E were based on curves of constant risk. Zone A is defined as the zone of “clinically accurate measurements with no effect on clinical action.” Measurements falling within zones C, D and E are associated with increasing risk with effect on clinical action.

Measurement bias provides an estimate of systematic measurement error (ISO 15197:2013). An estimation of bias was calculated as the mean of a series of measurements minus a reference quantity value (ISO 15197:2013).

Statistics. Bland-Altman analyses and linear regression analysis were used to assess system accuracy. The Parkes error grid (Pfützner et al. 2013) was used to assess clinical accuracy. Accuracy of each test was assessed, and subsequently data for each instrument were pooled. Measurement bias was calculated as the mean of all measures obtained for a given blood sample minus the reference value determined on the same sample using the IDEXX. Linear regression analyses were also performed for each sample, paired against the IDEXX reference value; significance was accepted at $p \leq 0.05$. Comparisons between the PBGMs were performed using one-way ANOVA and when a significant F ratio was obtained the Bonferroni post-hoc test (appropriate for samples of different size) was used.

Results

Main points:

- Bias of iPet PRO not different from zero (no significant bias); bias of other PBGMs different from zero
- System accuracy was excellent, and all criteria tested for were met
- Clinical accuracy was excellent, and met criteria for accurate testing of animals with both type I and type II diabetes

System accuracy

System accuracy of each of the three instruments and the IDEXX reference instrument was assessed by Bland-Altman analysis and linear regression analysis. The results for dogs are presented in Table 4 (iPet PRO, Fig. 1) and Table 5 (AlphaTRAK 2 {Fig. 2} and Performa {fig. 3}) and the results for cats are presented in Table 6 (iPet PRO, Fig. 4) and Table 7 (AlphaTRAK 2 {Fig. 5} and Performa {Fig. 6}).

Linear regression analysis and Bland-Altman analysis showed that each of the three PBGMs had good agreement with respect to the reference system. There were, however, significant differences in the performance of the three PBGMs.

Bland-Altman analysis showed that the bias of the iPet PRO was not significantly different from zero. The AlphaTRAK 2 showed a significant positive bias (i.e. regression line positive to the line of unity). In contrast, the Performa had a significant negative bias. Linear regression analysis also showed significantly less variability (greater r^2) and a slope closer to unity, for iPet PRO than for either AlphaTRAK 2 and Performa.

The standard deviation of measured values for each instrument was not different between instruments. However, the range between the lower and upper limits of agreement were significantly different between iPet PRO and AlphaTRAK 2; a narrow range is an indication of less variability between measured value and the 'true' value, and this is also exemplified in a lower r^2 value in linear regression analysis. The range between the lower and upper limits of measurement were significantly less with iPet PRO and Performa (not different) than for AlphaTRAK 2. The measurement bias and the measurement range are both further reflected in the bias presented for the 95% confidence intervals, which was highly and significantly positive for the AlphaTRAK 2 and highly and significantly negative for the Performa.

Clinical accuracy was assessed using the Parkes Error Grid analysis (Pfützner et al. 2013) and the results for dogs are shown in Fig. 7 and the results for cats are shown in Fig. 8. When 99% or more of the measured points lie within Zone A then the method is deemed clinically accurate for the purpose of testing animals with type I diabetes, while 95% of the points lie within Zone B then the method is deemed clinically accurate for the purpose of testing animals with type II diabetes.

Using the AlphaTRAK 2 system for all 49 dog samples, 4 of 49 (8%) points lay outside of Zone A (Fig. 1A). Using Performa, the number of points outside of Zone A was 7 (14%; Fig. 1B). For the iPet PRO, only 2 points (4%) lay outside of Zone A (Fig. 1C).

Using the AlphaTRAK 2 system for all 36 cat samples, 4 points (11%) lay outside of Zone A (Fig. 2A). Using Performa, the number of points outside of Zone A was 5 (14%; Fig. 2B). For the iPet PRO, 3 points (8%) lay outside of Zone A (Fig. 2C).

Table 4. Results of the Bland-Altman analysis and linear regression analysis (r^2, slope, intercept) for iPet PRO (compared to IDEXX reference) using blood samples from dogs.

Sample	**Bias**	**Std Dev**	**Limits of agreement**		**Bias 95% CI**		**r^2**	**slope**	**Inter-cept**
Non-diabetic and not spiked	0.3875	10.18	-19.56	20.34	-3.92	4.70	0.891	1.111	-10.5
	0.5125	9.38	-17.87	18.99	-3.46	4.48	0.902	1.094	-8.64
	1.5958	8.65	-15.35	18.54	-2.07	5.26	0.924	1.122	-10.3
	0.6375	9.35	-17.69	18.98	-3.32	4.60	0.915	1.135	-12.5
	3.0542	8.69	-13.98	20.09	-0.63	6.73	0.923	1.121	-8.71
	2.5125	9.09	-15.31	20.33	-1.34	6.36	0.927	1.157	-12.8
Mean ± SD	1.45 ± 1.13	9.22 ± 0.56	-16.6 ± 2.08	19.5 ± 0.80	-2.46 ± 1.31	5.36 ± 0.97	0.914 ± 0.014	1.12 ± 0.02	-10.6 ± 1.79
Spiked with glucose and the original samples	-7.8076	18.59	-44.2	28.6	-14.6	-0.98	0.984	0.950	5.39
	-7.8065	20.35	-47.7	32.1	-15.3	-0.33	0.981	0.942	7.47
	-7.8710	17.14	-41.5	25.7	-14.2	-1.58	0.987	0.947	6.24
	-7.7097	18.26	-43.5	28.1	-14.4	-1.00	0.985	0.947	6.30
	-3.7097	18.18	-39.4	31.9	-10.4	2.97	0.985	0.949	9.71
	-4.2903	16.68	-37.0	28.4	-10.4	1.84	0.988	0.949	9.10
Mean ± SD	-6.53 ± 1.97	18.2 ± 1.28	-42.2 ± 3.78	29.1 ± 2.46	-13.2 ± 2.21	0.15 ± 1.82	0.985 ± 0.002	0.947 ± 0.003	7.37 ± 1.72
All samples	-4.7490	16.62	-37.3	27.8	-9.52	0.02	0.988	0.952	5.41
	-4.9327	17.73	-39.7	29.8	-10.0	0.15	0.986	0.945	6.75
	-4.6265	15.36	-34.7	25.5	-9.03	-0.22	0.990	0.947	6.75
	-4.5449	16.10	-36.1	27.0	-9.17	0.08	0.989	0.952	5.77
	-1.4224	15.76	-32.3	29.5	-5.95	3.10	0.989	0.952	8.70
	-2.1571	15.27	-32.1	27.8	-6.54	2.23	0.990	0.948	8.89
Mean ± SD	-3.73 ± 1.53	16.1 ± 0.92	-35.4 ± 2.95	27.9 ± 1.60	-8.37 ± 1.69	0.89 ± 1.41	0.989 ± 0.002	0.949 ± 0.003	7.05 ± 1.46

Table 5. Results of the Bland-Altman analysis and linear regression analysis (r^2, slope, intercept) for AlphaTRAK 2 and Performa (compared to IDEXX reference) using blood samples from dogs.

Sample	**Bias**	**Std Dev**	**Limits of agreement**		**Bias 95% CI**		**r^2**	**slope**	**Inter-cept**
Non-diabetic and not spiked									
AlphaTRAK 2	5.2625	18.52	-31.0	41.6	-2.58	13.1	0.805	1.333	-27.2
	3.9292	17.83	-31.0	38.9	-3.62	11.5	0.811	1.314	-26.7
	6.4292	18.52	-29.9	42.7	-1.41	14.3	0.800	1.324	-25.1
Mean ± SD	Ω 5.21 ± 1.25	Ω 18.3 ± 0.40	*-30.6 ± 0.64	Ω 41.1 ± 1.20	-2.54 ± 1.11	Ω 13.0 ± 1.41	Ω 0.805 ± 0.006	Ω 1.32 ± 0.01	Ω-26.3 ± 1.10
Performa	**-17.00	9.175	*-35.0	**1.00	ΩΩ * -20.9	** -13.1	**0.870	**0.820	**0.570
Spiked with glucose and the original samples									
AlphaTRAK 2	13.387	28.89	-43.2	70.0	2.78	24.0	0.969	1.068	-4.59
	12.87	29.10	-44.1	69.8	2.20	23.5	0.970	1.071	-5.99
	15.065	29.58	-42.9	73.0	4.20	25.9	0.969	1.073	-4.18
Mean ± SD	Ω 13.8 ± 1.15	Ω 29.2 ± 0.35	-43.4 ± 0.62	Ω 70.9 ± 1.79	Ω 3.06 ± 1.03	Ω 24.5 ± 1.27	Ω 0.969 ± 0.001	Ω 1.071 ± 0.003	*-4.92 ± 0.95
Performa	** -27.07	ΩΩ 18.76	**-63.8	**9.70	**-34.0	** -20.2	ΩΩ 0.988	**0.919	*-5.71
All samples									
AlphaTRAK 2	12.50	28.68	-43.7	68.7	4.27	68.7	0.972	1.083	-5.09
	11.84	29.13	-45.3	68.9	3.48	20.2	0.972	1.088	-6.96
	14.52	10.17	-44.6	73.6	5.86	23.2	0.970	1.089	-4.48
Mean ± SD	Ω 13.0 ± 1.40	22.7 ± 10.8	Ω -44.5 ± 0.80	Ω 70.4 ± 2.78	Ω 4.53 + 1.21	Ω 37.4 ± 27.2	Ω 0.971 ± 0.001	Ω 1.087 ± 0.003	*-5.51 ± 1.29
Performa	**-24.69	16.87	**-57.8	**8.39	**-29.5	-19.8	0.990	**0.925	*-8.71

* Significantly different ($p \leq 0.05$) than iPet PRO

** significantly different ($p \leq 0.05$) than iPet PRO and AlphaTRAK 2

Ω significantly different than iPet PRO and Performa

ΩΩ significantly different ($p \leq 0.05$) than AlphaTRAK 2

Table 6. Results of the Bland-Altman analysis and linear regression analysis (r^2, slope, intercept) for iPet PRO (compared to IDEXX reference) using blood samples from cats.

Sample	**Bias**	**Std Dev**	**Limits of agreement**		**Bias 95% CI**		**r^2**	**slope**	**Inter-cept**
Non-diabetic and not spiked	-0.4211	16.60	-33.0	32.1	-8.46	7.62	0.946	1.238	-30.9
	0.2105	15.76	-30.7	31.1	-7.42	7.84	0.955	1.242	-30.8
	0.6316	15.85	-30.4	31.7	-7.04	8.31	0.941	1.204	-25.6
	0.1579	14.38	-28.0	28.3	-6.80	7.12	0.957	1.208	-26.6
	2.3158	12.57	-22.3	27.0	-3.77	8.40	0.966	1.185	-21.4
	2.6316	15.59	-27.9	33.2	-4.92	10.2	0.952	1.227	-26.5
Mean ± SD	0.921 ± 1.25	15.1 ± 1.44	-28.7 ± 3.67	30.6 ± 2.40	-6.40 ± ± 1.73	8.25 ± 1.07	0.953 ± 0.009	1.217 ± 0.029	-27.0 ± 3.56
Spiked with glucose and the original samples	-15.476	24.49	-63.5	32.5	-26.7	-4.29	0.971	0.924	5.62
	-16.333	26.19	-67.7	35.0	-28.3	-4.37	0.967	0.922	5.58
	-15.762	26.10	-66.9	35.4	-27.7	-3.84	0.965	0.940	1.04
	-16.286	27.09	-69.4	36.8	-28.7	-3.92	0.963	0.935	1.95
	-11.191	24.19	-58.6	36.2	-22.2	-0.14	0.972	0.925	9.87
	-12.619	23.71	-59.1	33.8	-23.4	-1.79	0.972	0.934	5.78
Mean ± SD	-14.6 ± 2.17	25.3 ± 1.35	-64.2 ± 4.57	35.0 ± 1.58	-26.2 + 2.72	-3.06 ± 1.72	0.968 ± 0.004	0.930 ± 0.007	4.97 ± 3.16
All samples	-7.5278	23.73	-54.0	39.0	-15.6	0.50	0.968	0.927	8.71
	-7.5833	24.88	-56.4	41.2	-16.0	0.84	0.965	0.922	9.94
	-7.1389	24.40	-55.0	40.7	-15.4	1.12	0.965	0.931	8.18
	-7.4444	24.88	-56.2	41.3	-15.9	0.97	0.964	0.929	8.45
	-4.1667	22.12	-47.5	39.2	-11.7	3.32	0.972	0.931	11.3
	-4.3056	23.22	-49.8	41.2	-12.2	3.55	0.969	0.932	10.8
Mean ± SD	-6.36 ± 1.65	23.9 ± 1.08	-53.2 ± 3.67	40.4 ± 1.06	-14.5 ± 1.97	1.72 ± 1.35	0.967 ± 0.003	0.929 ± 0.004	9.56 ± 1.31

Table 7. Results of the Bland-Altman analysis and linear regression analysis (r^2, slope, intercept) for AlphaTRAK 2 and Performa (compared to IDEXX reference) using blood samples from cats.

Sample	Bias	Std Dev	Limits of agreement		Bias 95% CI		r^2	slope	Inter-cept
Non-diabetic and not spiked									
AlphaTRAK 2	1.2105	22.67	-43.2	45.6	-9.76	12.2	0.875	1.232	-28.3
	0.1053	23.98	-46.9	47.1	-11.5	11.7	0.872	1.251	-33.4
	4.3158	23.45	-41.7	50.3	-7.04	15.7	0.890	1.289	-32.7
Mean ± SD	1.877 ± 2.18	Ω 23.4 ± 0.66	*-43.9 ± 2.68	Ω 47.7 ± 2.40	-9.43 ± 2.25	Ω 13.2 ± 2.18	Ω 0.879 ± 0.010	1.257 ± 0.029	-31.5 ± 2.77
Performa	** -15.105	**8.77	-32.3	**-10.9	** -19.4	** -10.9	0.960	**0.962	** -10.2
Spiked with glucose and the original samples									
AlphaTRAK 2	-7.0476	36.86	-79.3	65.2	-23.9	9.79	0.931	0.964	16.8
	-9.8095	35.26	-78.9	59.3	-25.9	6.29	0.936	0.952	3.58
	-9.2857	35.06	-78.0	59.4	-25.3	6.73	0.937	0.956	3.07
Mean ± SD	Ω -8.71 ± 1.47	Ω 35.7 ± 0.99	Ω -78.7 ± 0.67	Ω 61.3 ± 3.38	-25.0 ± 1.03	Ω 7.60 ± 1.91	Ω 0.935 ± 0.003	*0.957 ± 0.006	7.82 ± 7.78
Performa	** -21.905	**15.84	-53.0	**9.14	-29.1	** -14.7	**0.989	0.943	-6.00
All samples									
AlphaTRAK 2	-2.4722	32.44	-66.0	61.1	-13.4	8.50	0.938	0.970	4.23
	-4.3889	32.11	-67.3	58.5	-15.3	6.48	0.939	0.959	4.82
	-1.5000	32.32	-64.9	61.9	-12.4	9.44	0.937	0.950	9.64
Mean ± SD	Ω -2.79 ± 1.47	Ω 32.3 ± 0.17	Ω -66.1 ± 1.20	Ω 60.5 ± 1.78	-13.7 ± 1.47	Ω 8.14 ± 1.51	Ω 0.938 ± 0.001	*0.960 ± 0.010	6.23 ± 2.97
Performa	** -19.611	**13.60	-46.3	**7.05	** -24.2	** -15.0	**0.990	*0.952	**-8.93

* Significantly different ($p \leq 0.05$) than iPet PRO

** significantly different ($p \leq 0.05$) than iPet PRO and AlphaTRAK 2

Ω significantly different than iPet PRO and Performa

ΩΩ significantly different ($p \leq 0.05$) than AlphaTRAK 2

Discussion

The results of this study showed that measured blood glucose concentrations (in plasma equivalence) obtained by the either of the three PBGMs used were not significantly different from the clinical testing laboratory-based reference method. There were, however, significant performance differences between the three PBGMs, with the iPet PRO demonstrating superior performance compared to the AlphaTRAK 2 and the Performa. The iPet PRO showed significantly less bias than the other two instruments, with a linear regression line that was not different from the line of unity. The results obtained with the iPet PRO were also less variable than those obtained by the other two PBGMs.

The iPet PRO is a relatively new device recently introduced to the veterinary / home care market. The AlphaTrak 2 was introduced in 2008 for the veterinary market and was demonstrated to be superior in performance to a human PBGM when cat blood samples were assessed (Zini et al. 2009). In an assessment of four PBGMs using blood samples from non-diabetic and diabetic cats and dogs, Kang et al. (2016) reported that the AlphaTRAK 2 “appeared to be the most accurate”. The AlphaTRAK 2 and Performa (Accu-Chek) were also assessed using dog blood samples by Cohen et al. (2009). The found that all 6 PBGMs had significant bias compared to the clinical reference method, as well as substantial differences in accuracy.

The analyses of the results were performed with reference to the ISO 15197 standard (ISO 15197:2013). The study design was very limited in this regard, and the following main limitations were identified:

- Only one instrument was tested
- Only 3 test strips were tested for each blood sample
- Precision was not determined
- Repeatability was not determined
- Reproducibility was not determined
- Traceability of the reference method was not provided
- Results from tests of control solutions have not been provided
- Traceability of control solutions for reference method (IDEXX) not provided

It is concluded that the iPet PRO PBGM provided excellent results compared to the clinical reference method, and is an excellent choice for veterinary or home-based glucose monitoring of dogs and cats.

References

Cohen TA, Nelson RW, Kass PH, Christopher MM, Feldman EC. Evaluation of six portable blood glucose meters for measuring blood glucose concentration in dogs. J Am Vet Med Assoc. 2009 Aug 1;235(3):276-80.

Domori A, Sunahara A, Tateno M, Miyama TS, Setoguchi A, Endo Y. The clinical utility of two human portable blood glucose meters in canine and feline practice. Vet Clin Pathol. 2014 Mar;43(1):55-62.

Inoue S, Egi M, Kotani J, Morita K. Accuracy of blood-glucose measurements using glucose meters and arterial blood gas analyzers in critically ill adult patients: systematic review. Crit Care. 2013 Mar 18;17(2):R48.

ISO 15197:2013. ISO 15197:2013(E). In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. International Standards Organization, Geneva, Switzerland.

Johnson BM, Fry MM, Flatland B, Kirk CA. Comparison of a human portable blood glucose meter, veterinary portable blood glucose meter, and automated chemistry analyzer for measurement of blood glucose concentrations in dogs. J Am Vet Med Assoc. 2009 Dec 1;235(11):1309-13.

Kang MH, Kim DH, Jeong IS, Choi GC, Park HM. Evaluation of four portable blood glucose meters in diabetic and non-diabetic dogs and cats. Vet Q. 2016;36(1):2-9.

Peterson ME, Eirmann L. Dietary management of feline endocrine disease. Vet Clin North Am Small Anim Pract. 2014 Jul;44(4):775-88.

Wess G, Reusch C. Evaluation of five portable blood glucose meters for use in dogs. J Am Vet Med Assoc. 2000 Jan 15;216(2):203-9.

Zini E, Moretti S, Tschuor F, Reusch CE. Evaluation of a new portable glucose meter designed for the use in cats. Schweiz Arch Tierheilkd. 2009 Sep;151(9):448-51.

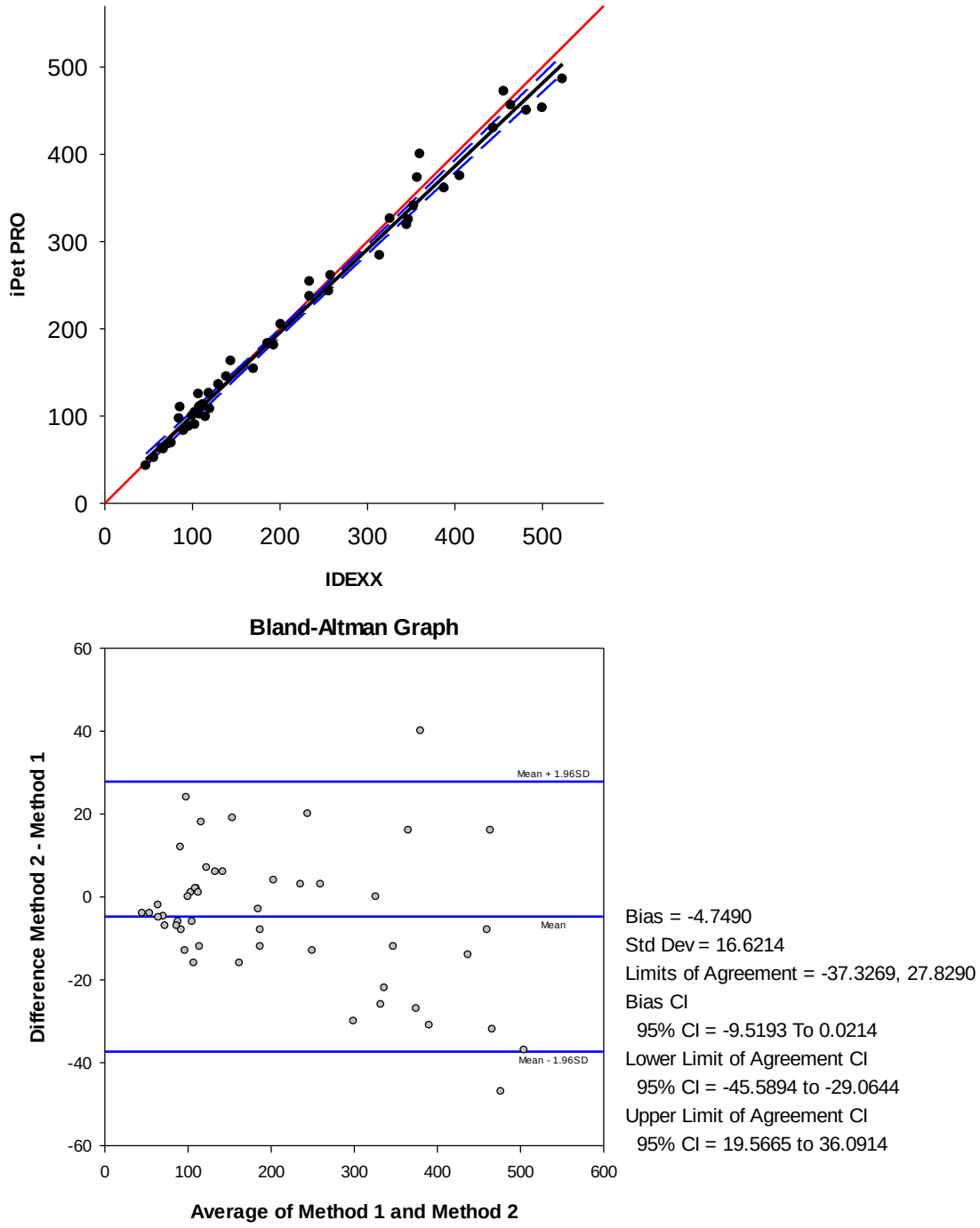

Figure 1. Bland-Altman analysis of all dog blood samples (n = 49) using iPet PRO with test strips from lot MPU1226001.

Top panel: The solid red line is the line of unity. The red line is the linear regression line, and the dashed blue lines show 95% confidence intervals.

Bottom Panel: the solid blue lines show the 95% confidence intervals.

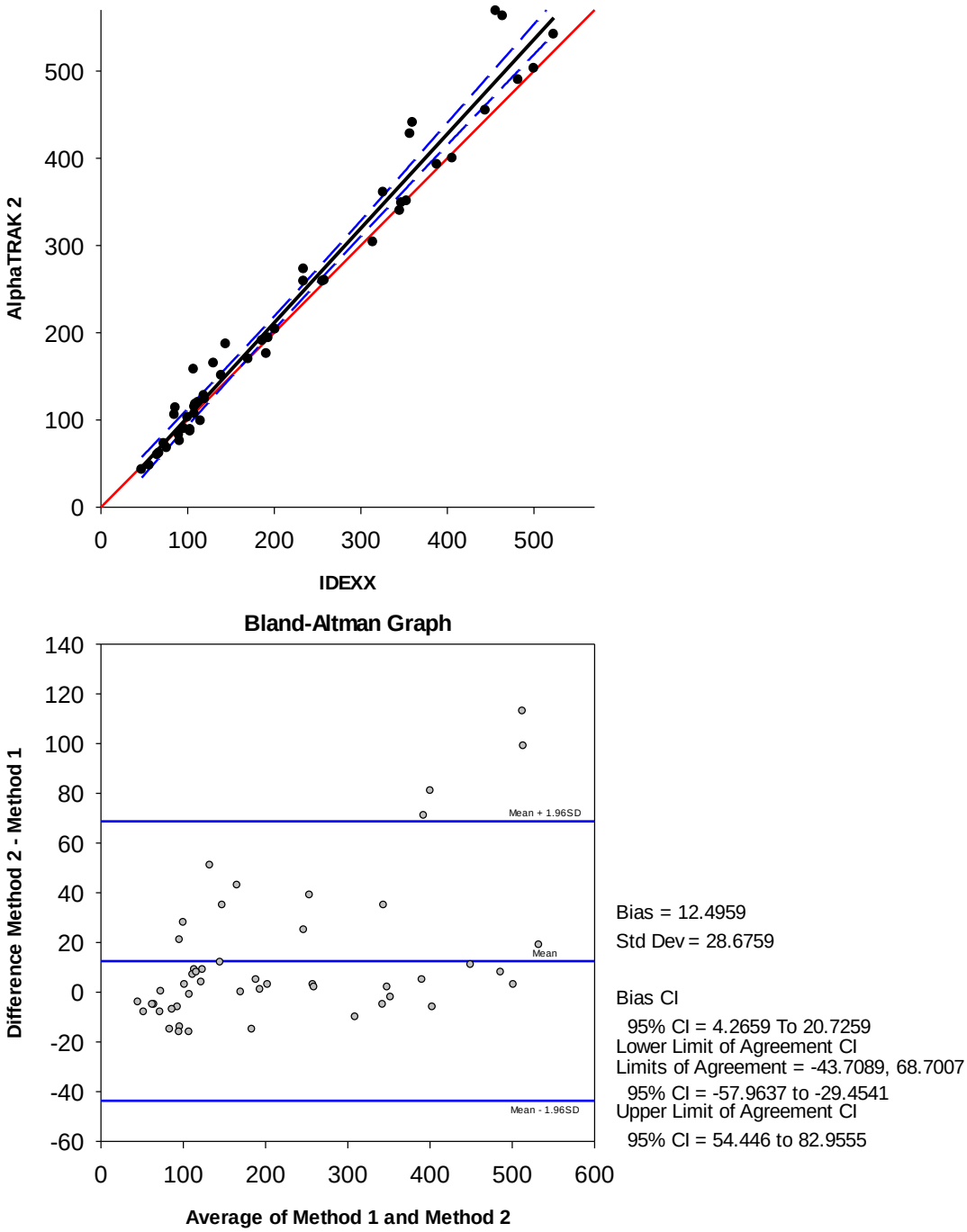

Figure 2. Bland-Altman analysis of all dog blood samples (n = 49) using AlphaTRAK 2 with test strips from lot 1532809.

Top panel: The solid red line is the line of unity. The red line is the linear regression line, and the dashed blue lines show 95% confidence intervals.

Bottom Panel: the solid blue lines show the 95% confidence intervals.

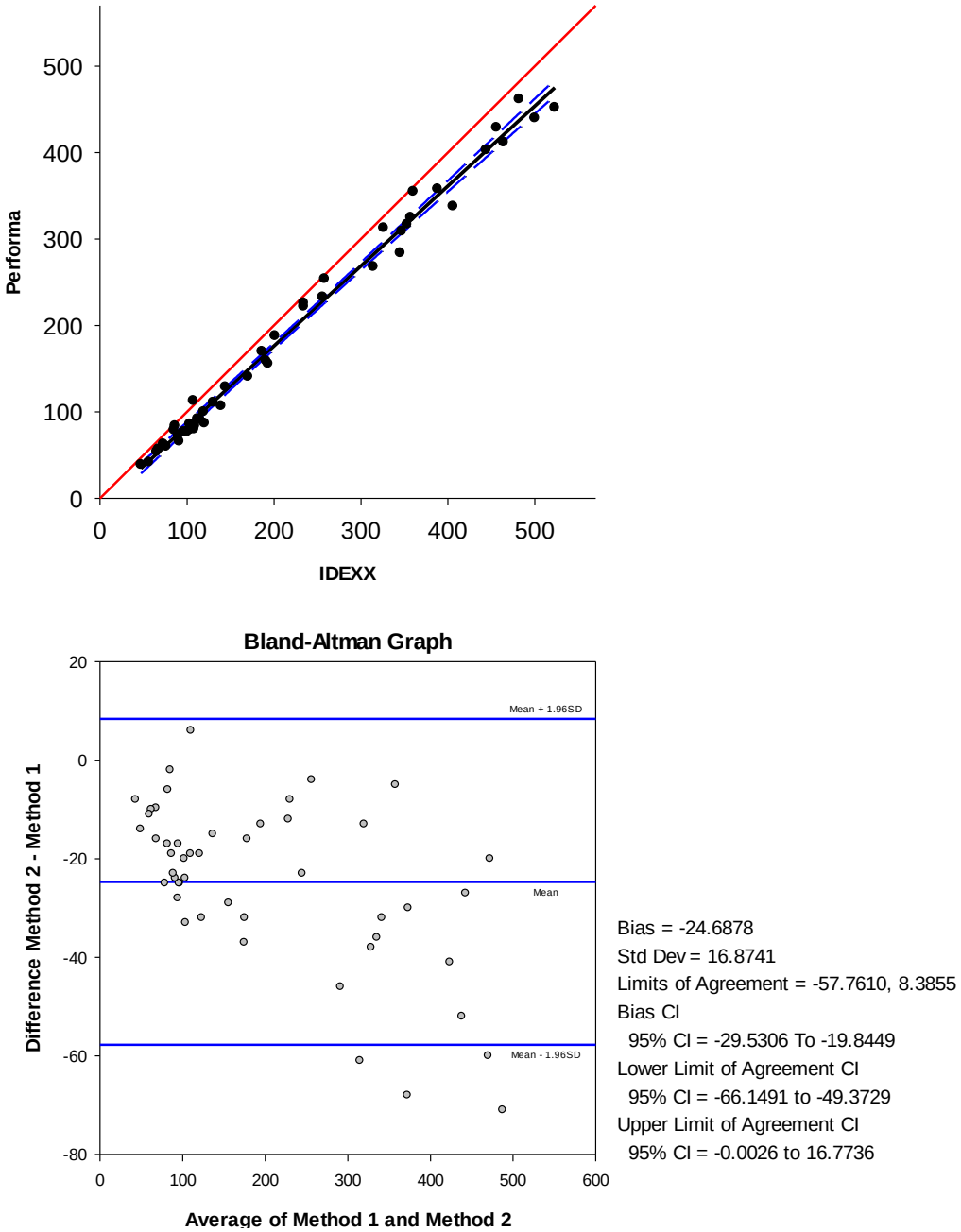

Figure 3. Bland-Altman analysis of all dog blood samples (n = 49) using Performa with test strips from lot 475203.

Top panel: The solid red line is the line of unity. The red line is the linear regression line, and the dashed blue lines show 95% confidence intervals.

Bottom Panel: the solid blue lines show the 95% confidence intervals.

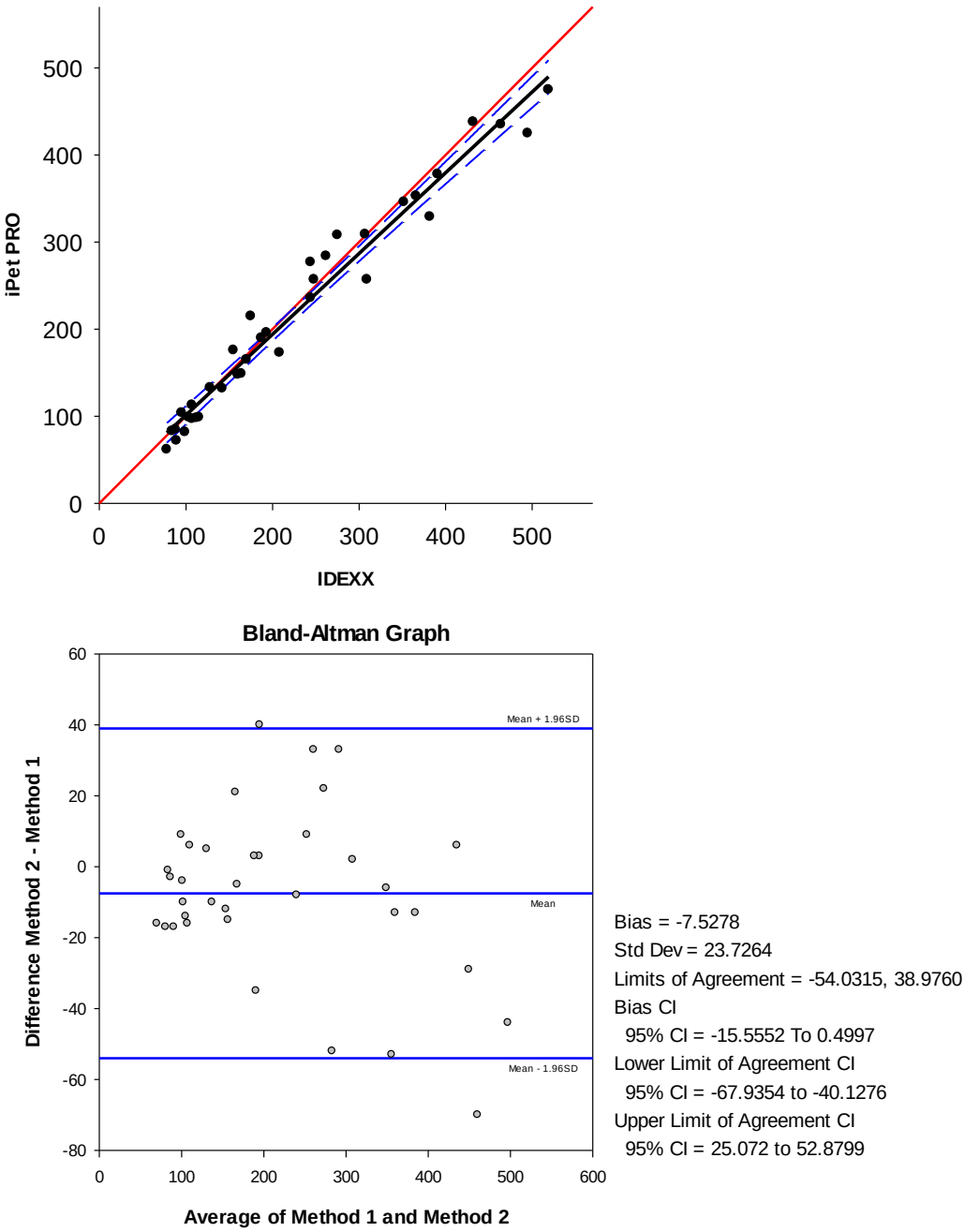

Figure 4. Bland-Altman analysis of all cat blood samples (n = 36) using iPet PRO with test strips from lot MPU1226001.

Top panel: The solid red line is the line of unity. The red line is the linear regression line, and the dashed blue lines show 95% confidence intervals.

Bottom Panel: the solid blue lines show the 95% confidence intervals.

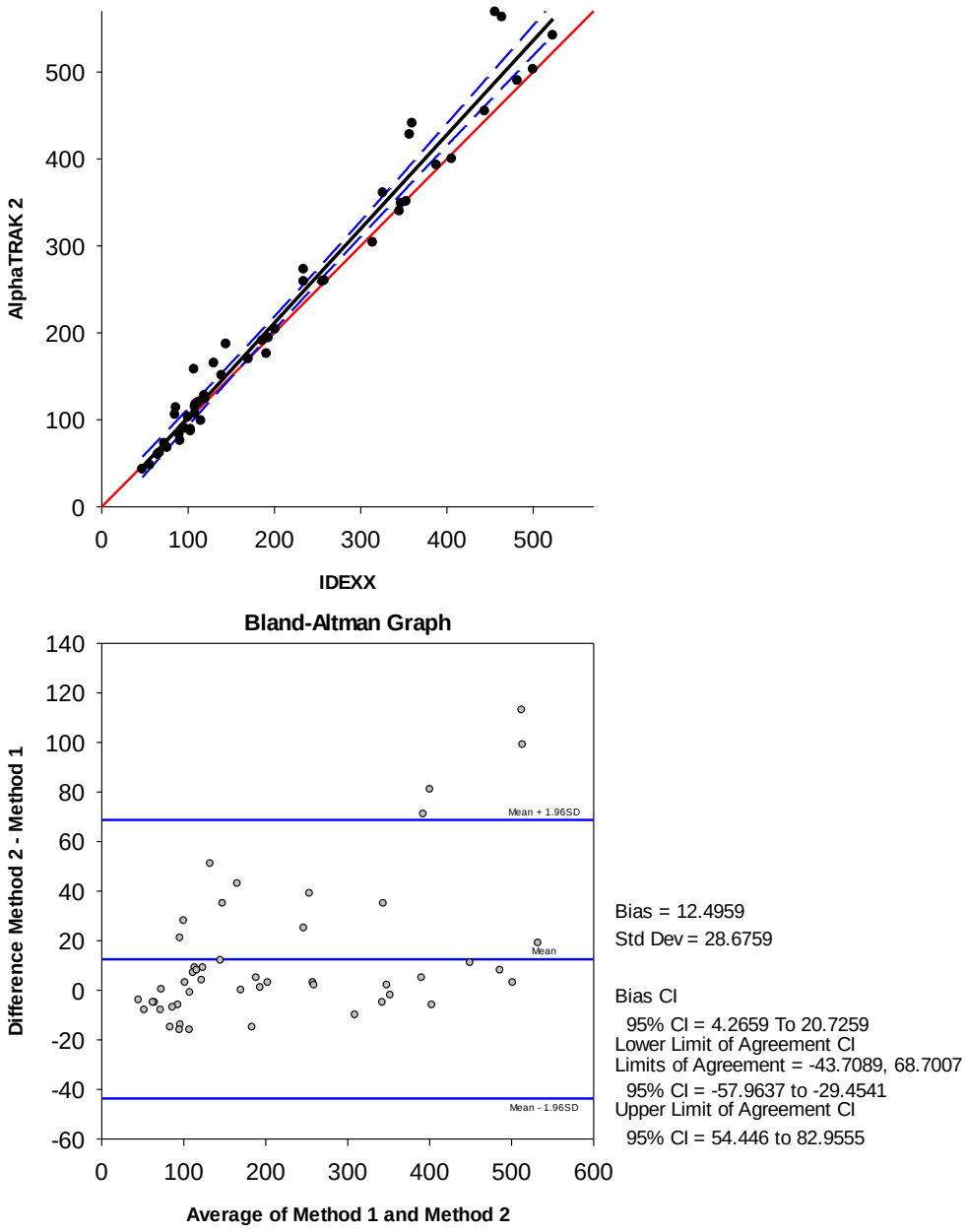

Figure 5. Bland-Altman analysis of all cat blood samples (n = 36) using AlphaTRAK 2 with test strips from lot 1532809.

Top panel: The solid red line is the line of unity. The red line is the linear regression line, and the dashed blue lines show 95% confidence intervals.

Bottom Panel: the solid blue lines show the 95% confidence intervals.

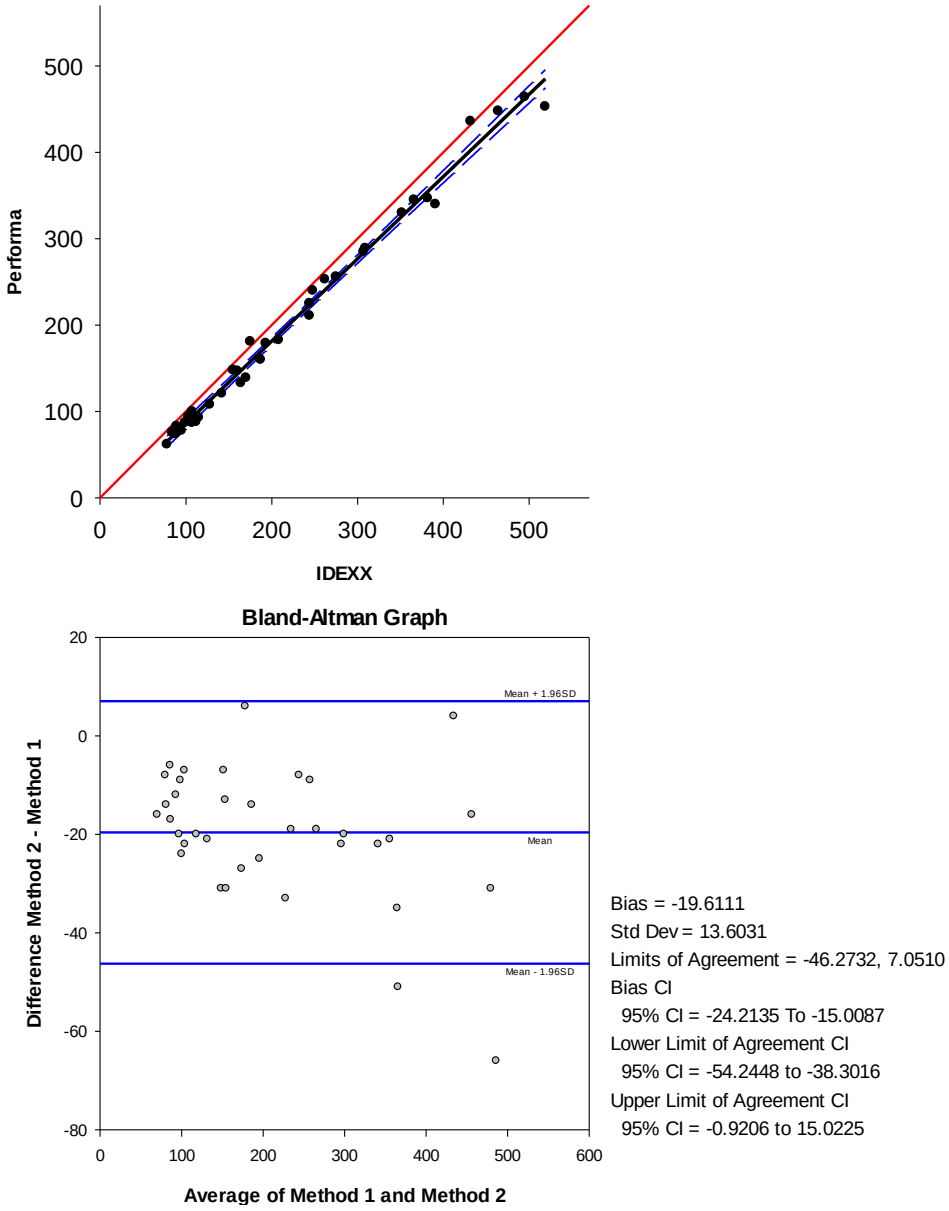

Figure 6. Bland-Altman analysis of all cat blood samples (n = 36) using Performa with test strips from lot 475203.

Top panel: The solid red line is the line of unity. The red line is the linear regression line, and the dashed blue lines show 95% confidence intervals.

Bottom Panel: the solid blue lines show the 95% confidence intervals.

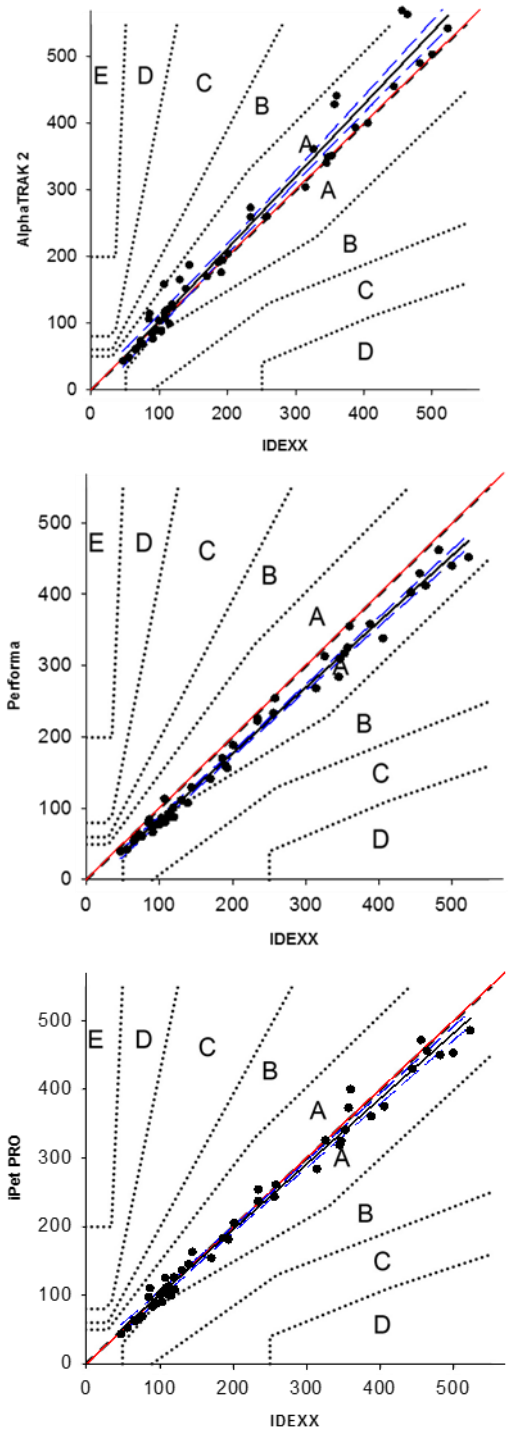

Figure 7. Parkes error grid analysis of all dog blood samples (n = 49) using AlphaTRAK 2 with test strips from lot 1532809 (top panel), Performa with test strips from lot 475203 (middle panel), and iPet PRO with test strips from lot MPU1226001 (bottom panel). Line of unity is shown by the solid red line. The linear regression line is shown in red. The 95% confidence intervals are shown by dashed blue lines. See text for explanation of zones A to E.

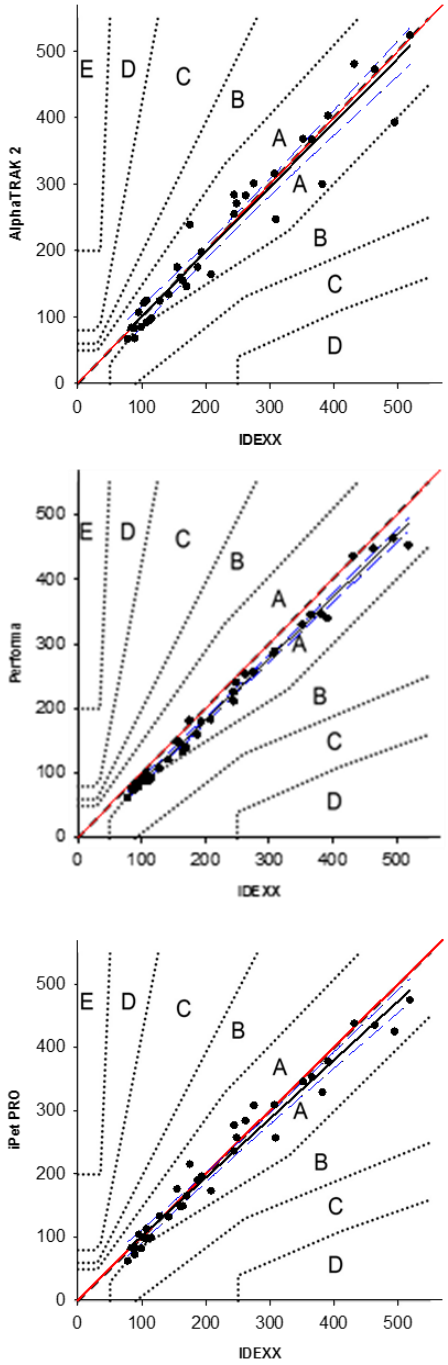

Figure 8. Parkes error grid analysis of all cat blood samples (n = 36) using AlphaTRAK 2 with test strips from lot 1532809 (top panel), Performa with test strips from lot 475203 (middle panel), and iPet PRO with test strips from lot MPU1226001 (bottom panel). Line of unity is shown by the solid red line. The linear regression line is shown in red. The 95% confidence intervals are shown by dashed blue lines. See text for explanation of zones A to E.